IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[UNDER SEAL]	:	CIVIL ACTION NO. C 9-4672
Plaintiff	:	
v.	:	FILED UNDER SEAL
[UNDER SEAL]	:	
Defendants.	:	

FIRST AMENDED QUI TAM COMPLAINT

FILED UNDER SEAL

DO NOT FILE WITH PACER

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, EX REL. ANTHONY R. SPAY	:
	: CIVIL ACTION NO. : 09-4672
Plaintiffs,	:
v.	:
CVS CAREMARK CORPORATION, CAREMARK Rx, LLC (f/k/a CAREMARK Rx, INC.), CAREMARK, LLC (f/k/a/ CAREMARK, INC.) SILVERSCRIPT, LLC (f/k/a SILVERSCRIPT INC.),	: FIRST AMENDED QUI TAM COMPLAINT
	: JURY TRIAL DEMANDED
	: FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)
Defendants.	:
	: HON. RONALD L. BUCKWALTER

I. INTRODUCTION

Qui Tam Plaintiff/Relator Anthony R. Spay, through his counsel, Pietragallo Gordon Alfano Bosick & Raspanti, LLP, on behalf of the United States of America, brings his First Amended Complaint against Defendant CVS Caremark Corporation, Defendant Caremark Rx, LLC (f/k/a Caremark Rx, Inc.), Defendant Caremark LLC (f/k/a Caremark, Inc.), Defendant SilverScript, LLC (f/k/a SilverScript, Inc.), and alleges based upon his own direct and independent knowledge:

1. This is an action to recover damages and civil penalties on behalf of the United States of America, arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used, or presented by Defendants CVS Caremark Corporation, Caremark Rx, LLC (f/k/a Caremark Rx, Inc., Caremark LLC (f/k/a Caremark, Inc.), SilverScript, LLC (f/k/a SilverScript, Inc.) (collectively referred to as the "Defendants"), and/or

their agents, predecessors, successors, and employees in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 et seq., as amended ("the FCA" or "the Act").

2. Defendants, in their role as Pharmacy Benefits Manager ("PBM") for Medicare Part D Sponsors throughout the United States and in the Commonwealth of Puerto Rico have intentionally, systematically, recklessly and illegally provided false or fraudulent Medicare Part D claims and prescription drug event ("PDE") data to the Centers for Medicare and Medicaid Services ("CMS") since 2006.

3. As a direct result of Defendants' fraudulent, improper and illegal practices, Federal health insurance programs including, but not limited to, Medicare Part D, have been caused and continue to:

A. pay false or fraudulent claims related to Part D prescription drugs that would not have been paid but for the Defendants' intentional, illegal, improper, and reckless business practices;

B. pay increased subsidies to Medicare Part D Plan Sponsors, including Medical Card System, Inc. and/or MCS Life Insurance Company, through: direct advance monthly payments; reinsurance subsidies; low-income cost-sharing subsidies (or grants for low-income Part D individuals received in lieu of low-income subsidies); risk-sharing arrangements; year-end retroactive adjustments and reconciliations; and/or reinsurance payments made for private fee-for-service plans;

C. based on the Defendants' false representations of compliance with Federal laws and regulations related to the Part D program, enter into contracts with the Defendants as providers of Part D services, whether as a Sponsor, PBM, or

other downstream entity, including but not limited to, CMS's Electronic Data Interchange ("EDI") Agreement, and/or other agreements which are necessary for Part D providers to submit claims or data to CMS and/or to receive payments related to the Medicare Part D program.

4. Defendants utilize an automated nationwide claims adjudication system in all States, as well as the Commonwealth of Puerto Rico, where the Defendants provide PBM services, and, as a result, the Defendants' illegal and improper practices have also caused the Federal government to pay false or fraudulent claims in Federal health insurance programs, in addition to Part D, which provide prescription drug benefits to their beneficiaries, including, but not limited to CHAMPUS/TRICARE, CHAMPVA, and the Federal Employee Health Benefits Program.

5. As a direct and foreseeable result of the Defendants' improper and illegal practices, Federal and state health insurance programs, including but not limited to, Medicare and Medicaid, have been impacted by Defendants' adjudication of Part D claims by virtue of the States' contributions to low income cost subsidies.

6. Plaintiff seeks through this action to recover on behalf of the United States damages and civil penalties arising from Defendants' making or causing to be made false or fraudulent records, statements and/or claims in connection with its knowing violations of the Medicare Part D Program reporting requirements and claims submissions for Part D benefits.

7. Pursuant to 31 U.S.C. § 3730(c)(3), if the Government elects not to intervene in a qui tam action, the Relator has the right to proceed against the Defendant on behalf of the Government. The Court may later permit the Government to intervene upon a showing of good cause. In a non-intervened matter, the Government, and, therefore, the American taxpayer, still

receives at least 70% of any recovery obtained through the qui tam Relator's efforts pursuant to 31 U.S.C. § 3730(d)(2).

II. THE PARTIES

A. Relator/Plaintiff

8. Plaintiff/Relator Anthony R. Spay is a resident of the State of New Jersey and a citizen of the United States.

9. Relator Spay is a duly licensed pharmacist under the laws of Pennsylvania, with 37 years of diversified experience within the pharmacy industry. He is uniquely qualified to bring this action on behalf of the United States.

10. Relator's knowledge of the pharmacy industry emanates from three decades of experience since becoming a licensed pharmacist encompassing retail practice, benefits management, long-term care, behavioral health, executive management, prescription drug fraud/abuse detection, auditing and recovery for many of the nation's largest payers and pharmacy claims processors.

11. After receiving his pharmacy degree, Relator Spay spent over seven years as retail Pharmacy Manager with Eckerd Drugs (1967-74). Drawing on this knowledge and experience, Mr. Spay later owned and operated his own chain of retail pharmacies for twenty years (1974 to 1994).

12. Following his successful career as a retail pharmacist, Mr. Spay founded and served as President of Managed Care Consultants (1994 to the present), where he has continued his involvement with community mental health issues. Mr. Spay is also a consultant and board member for a behavioral health organization.

13. In addition to operating two retail pharmacies, Relator served as President of

Squire Medical Services (1995-1999), a long term care supplier with seven locations.

14. For over 17 years, Relator dedicated himself to co-founding, developing, and managing Pharm/DUR Inc., a corporation headquartered in Philadelphia, PA.

15. Mr. Spay co-founded Pharm/DUR Inc. in 1992 to administer many aspects of pharmaceutical management programs for insurers, employer groups, and commercial and government-sponsored health plans. Under Relator's leadership as President and Chief Executive Officer, Pharm/DUR Inc. became one of the largest providers of pharmacy prescription benefit audit and recovery services in the United States with auditors across the country.

16. Relator has extensive experience designing and implementing drug auditing protocols, fraud detection methods, software, and supporting training systems for the identification and investigation of prescription drug fraud, waste and abuse – both retrospectively and prospectively.

17. Under Relator's guidance, Pharm/DUR and its successor companies' clients have included some of the largest pharmaceutical benefit management firms, HMOs and private insurance firms in the United States. Pharm/DUR Inc. has conducted in excess of 100,000 in-store audits nationwide, in addition to numerous desk audits, program reviews and retrospective forensic electronic data analyses and audits. Annually, the Company has conducted approximately 15,000 in-store audits in a minimum of 35 states.

18. Pharm/DUR Inc. and its successor companies have used a proprietary system application, AUDITRAC Automated Healthcare System ("AUDITRAC"), which utilizes the paid claims data from Pharm/DUR's clients to develop targeted pharmacy audits.

19. Relator is a current and former member of many local and national professional scientific societies. He is a current and former Fellow of the American College of Apothecaries

and of the Compounding Pharmacists of America, a Board Member of Crisis Management Services, Inc., a member of the National Association of Retail Druggists, an Executive Board Member of the Philadelphia Association of Retail Druggists, and an Education Committee Member of the Pharmacist Association.

20. On or about July 1, 2009, Affiliated Computer Services ("ACS") acquired Pharm/DUR Inc. Following the ACS acquisition, Pharm/DUR's audit operations continued to be operated by Pharm/DUR's existing management team, including the Relator, who stayed with the new company as a Managing Director.

21. ACS was acquired by The Xerox Corporation in February of 2010. Relator Spay retired from ACS in May of 2011.

B. Defendants

1. Defendant CVS Caremark Corporation

22. Defendant CVS Caremark Corporation (hereafter "CVS Caremark"), the largest provider of prescriptions and related healthcare services in the United States, is incorporated under the laws of the state of Delaware, and headquartered at One CVS Drive, Woonsocket, Rhode Island 02895.

23. CVS Caremark was formed on March 22, 2007, as the result of a merger between CVS Corporation and Defendant Caremark, Rx, Inc. At that time, Defendant Caremark Rx, Inc. was merged with CVS Corporation and into a newly-formed subsidiary of CVS Corporation, Caremark Rx, LLC, with the CVS subsidiary continuing as the surviving entity. Following the merger, the merged company changed its name to "CVS Caremark Corporation."

24. CVS Caremark has reported to the public that since at least 2007, it has been the largest provider of prescription and related healthcare services in the United States, having filled

or managed more than one billion prescriptions since that time.

25. CVS Caremark operates two business segments: retail pharmacy and pharmacy services. In 2010, Defendant CVS Caremark's PBM filled or managed approximately 585 million prescriptions. That same year, its retail pharmacy segment filled approximately 636 million retail prescriptions, which accounted for 18% of the entire U.S. pharmacy market.

26. In its retail pharmacy segment, CVS Caremark operates a national retail pharmacy network with over 60,000 participating pharmacies, including more than 6,000 retail CVS pharmacy stores. CVS Caremark also operates an on-line pharmacy, CVS.com®, and mail order and specialty pharmacies.

27. CVS Caremark's Pennsylvania operations include 384 retail stores, one specialty pharmacy store, and two specialty mail order facilities.

28. In its pharmacy services business, CVS Caremark offers a full range of pharmacy benefit management ("PBM") services. The PBM business generates revenues for CVS Caremark primarily from dispensing prescription drugs and performing related services for which it receives certain fees. These PBM services include mail order pharmacy services, specialty pharmacy services, plan design and administration, formulary management, and claims processing. For calendar year 2007, CVS Caremark's largest customer was the Federal Employees Health Benefits Program ("FEHBP"). It continues to be one of its largest customers.

29. CVS Caremark has been administering the retail pharmacy benefit program for the largest FEHBP Plan, the Blue Cross and Blue Shield Government-wide Service Benefit Plan, (also known as the Federal Employee Program ("FEP")) since 1993.

30. In late 2009, Defendant CVS Caremark's contract with FEP was extended through the end of 2011. A new agreement, announced in May of 2011, further extends CVS

Caremark's contract with the FEP through 2014, and includes mail-order pharmacy and specialty pharmacy services on top of retail pharmacy benefit services, including network contracting and management of customized clinical programs.

31. All prescriptions managed by CVS Caremark, whether filled at one of its own mail service pharmacies or through its own retail pharmacy, are uniformly and systematically analyzed, processed and documented by CVS Caremark's nationwide proprietary prescription management systems.

32. According to CVS Caremark's own financial reports, these uniform computerized prescription management systems assist staff and network pharmacists in the processing of prescriptions by automating tests for various items, including plan eligibility, early refills, duplicate dispensing, appropriateness of dosage, drug interactions or allergies, over-utilization and potential fraud issues.

2. CVS Caremark Entities Participating in Medicare Part D Program

33. Currently, Defendant CVS Caremark participates in the Medicare Part D prescription drug program in several significant ways. Attached as Exhibit "A" is an organizational chart describing the CVS Caremark entities involved in its Medicare Part D business. Since 2006, CVS Caremark has provided Part D PBM services to CVS Caremark's clients' Part D Plans through the following subsidiaries: * SilverScript, Inc; Caremark LLC; CaremarkPCS; CVS Caremark Part D Services, LLC; and RxAmerica, LLC.

34. Since 2006, CVS Caremark has served as a Medicare Prescription Drug Plan ("PDP") Sponsor that contracts with Medicare to provide prescription drug benefits in all 50 states, the District of Columbia, and Puerto Rico, through SilverScript Insurance Company ("SSIC") and Accendo Insurance Company ("Accendo").

35. CVS Caremark acquired Accendo. Effective January 1, 2009, Accendo replaced RxAmerica® as the Medicare-approved prescription drug plan for the RxAmerica Medicare Part D drug benefit plans.

36. In addition, CVS Caremark operates thousands of retail pharmacies, as well as mail order and specialty pharmacies that process Part D prescriptions and dispense Part D drugs to Medicare beneficiaries.

37. Since 2006, through its subsidiary, SSIC, a Medicare Part D Prescription Drug Plan ("PDP") Sponsor, CVS Caremark has provided Medicare Part D drug benefits to eligible beneficiaries.

38. SSIC and Accendo are PDPs that contract with Medicare to provide prescription drug plans in all 50 states, the District of Columbia, and Puerto Rico.

39. In December 2010, CVS Caremark announced an agreement to acquire the Medicare Part D business of Universal American Corp. ("UAM Medicare Part D business") for approximately $1.25 billion. This acquisition was completed on April 29, 2011. Through its UAM Medicare Part D business, CVS Caremark provides Medicare prescription drug benefits to more than three million beneficiaries though the Community CCRxSM prescription drug plan.

3. Defendant CVS Caremark's PBM Subsidiary, Caremark Rx

40. Defendant Caremark Rx, LLC (f/k/a Caremark Rx, Inc.) (hereafter "Caremark Rx") is one of the largest pharmaceutical services companies in the United States. It is incorporated under the laws of the state of Delaware, with its principal executive offices located at 211 Commerce Street, Suite 800, Nashville, Tennessee, 37201. Caremark Rx is the parent of CVS Caremark's pharmacy services subsidiaries.

41. In 2006, and prior to the March 2007 merger, Caremark Rx, was one of the largest

pharmaceutical services companies in the United States with net revenues exceeding $36 billion. As of December 31, 2006, Caremark Rx employed more than 13,000 people.

42. Caremark Rx's pharmaceutical services are referred to as pharmacy benefit management ("PBM") services, and include both the facilitation of dispensing prescription drugs to eligible participants in benefit plans maintained by its customers, as well as the provision of drug benefits to eligible beneficiaries under the Federal government's Medicare Part D Program.

43. In short, Caremark Rx, through its subsidiaries, operates mail order, specialty mail order and retail specialty pharmacy subsidiaries, all of which conduct business throughout the United States and/or its legal territories.

44. The pharmacy services segment of CVS Caremark's business includes the provision of products and services to managed care entities that provide services to beneficiaries of Medicare, Medicaid, and other government-sponsored healthcare programs, as well as employers who qualify for the retiree drug subsidy.

45. CVS Caremark participates in the administration of Medicare (Part D) Drug Benefit through Caremark Rx. Caremark Rx's PBM services are provided to its health plan clients and other clients that have qualified as Medicare Part D drug Plans, or PDPs. Caremark Rx's customers are primarily sponsors of health benefit plans (employers, unions, government employee groups, insurance companies, and managed care organizations).

46. CVS Caremark also participates extensively in the Medicare Part D Program by assisting employer, union, and other health plan clients that qualify for the Medicare Part D retiree drug subsidy by collecting and submitting eligibility and/or drug cost data to CMS as required under Part D in order for these employer, union, and other health plan clients to obtain Part D retiree drug subsidies.

a. Caremark Rx Provides Its Part D PBM Services Through A Subsidiary SilverScript, LLC

47. Defendant SilverScript, LLC (f/k/a SilverScript, Inc.) (hereafter "SilverScript") is a Delaware limited liability company with its principal place of business at 2211 Sanders Road, Northbrook, IL 60062.

48. From before January 1, 2006 through March 22, 2007, SilverScript was a wholly-owned subsidiary of Caremark Rx. SilverScript is now a wholly-owned subsidiary of Defendant CVS Caremark.

49. Since 2006, Defendant Caremark Rx, through SilverScript, has provided PBM services to Part D Plan Sponsors throughout the country. These Part D Plan Sponsors include, at times relevant to this matter, Medical Card System, Inc. (hereafter "MCS") and its affiliated PDP Sponsor, MCS Life. MCS is a for profit corporation registered in the Commonwealth of Puerto Rico. See paragraphs 65-78, infra.

50. During 2006 alone, Caremark Rx managed more than 516 million prescriptions for individuals from more than 2,000 organizations, including its largest customer, the FEHBP, which accounted for more than 16% of Defendant Caremark Rx's net revenue.

51. During 2006, Caremark Rx derived substantially all of its net revenue from dispensing prescription drugs to eligible participants in benefit plans maintained by its health plan sponsor customers and to individuals throughout the United States.

52. SilverScript provides managed PBM services to Part D Plan Sponsors throughout the country, including, at times relevant to this matter, to MCS Life. Following the March 2007 merger, Caremark Rx continued to provide these same services through its subsidiaries, which then operated as subsidiaries of the newly-formed entity, CVS Caremark.

53. From 2006 until sometime just prior to 2009, CVS Caremark provided Part D

PBM services through its subsidiary SilverScript. Sometime before 2009, CVS Caremark's Part D PBM was known as and doing business as "CVS Caremark Part D Services, LLC." CVS Part D Services, LLC, is a Delaware limited liability corporation with a registered agent located at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

b. Other CVS Caremark Entities Providing Part D PBM Services

54. Defendant Caremark, LLC (f/k/a Caremark, Inc.) (hereafter "Caremark") is a California limited liability company which has its principal place of business at 2211 Sanders Road, Northbrook, IL 60062. Caremark is a wholly-owned subsidiary of CVS Caremark.

55. In 2006 and before the March 2007 CVS-Caremark merger, Defendant Caremark Rx conducted its pharmaceutical services operations through its subsidiaries, including but not limited to, Caremark, Inc. (now Defendant Caremark LLC) and CaremarkPCS (f/k/a AdvancePCS).

4. Defendant CVS Caremark's Medicare Part D Plan (PDP) Sponsor, SilverScript Insurance Company

56. CVS Caremark additionally participates in the Medicare Part D Program through the offering of Medicare Part D benefits by its subsidiary, SilverScript Insurance Company, a subsidiary of SilverScript.

57. In 2005, Defendant Caremark Rx through its subsidiaries Caremark and SilverScript, formed SilverScript Insurance Company to participate as a Part D Plan (PDP) under the Medicare Drug Benefit. In 2006, SilverScript Insurance Company obtained a license from the State of Tennessee to operate as a health insurance company.

58. Since 2006, Defendant CVS Caremark has participated in Medicare Part D prescription program through the offering of Medicare Part D pharmacy benefits by its subsidiary, SilverScript Insurance Company, which has been approved by CMS as a prescription

drug plan (PDP) Sponsor under Medicare Part D in all regions of the United States.

59. SilverScript Insurance Company, a direct wholly-owned subsidiary of CVS Caremark Corporation, now offers Part D Plans in all 50 states, Washington D.C. and Puerto Rico. For the year ended 2008, SilverScript Insurance Company was licensed in Pennsylvania, which represented $47.8 million in direct written business for Part D Plans, SilverScript's second-highest market next to New York state.

60. SilverScript Insurance Company, a national Part D Sponsor, and SilverScript, Inc., a Medicare Part D pharmacy benefit management company (PBM), are both subsidiaries of CVS Caremark.

5. CVS Caremark Revenues Related to Medicare Part D Services

61. CVS Caremark Defendants participate in the Federal government's Medicare Part D program as a PDP and as a PBM. CVS Caremark's net revenues include both Part D payments received from CMS, as well as payments received from Part D Sponsors related to CVS Caremark's subsidiaries' Part D PBM services.

62. CVS Caremark's Part D insurance premiums earned by its PDPs, are set based on the PDP's annual bid and related contractual arrangements with the Centers for Medicare and Medicaid Services ("CMS"). The Part D insurance premiums include a direct premium paid by CMS to CVS Caremark's subsidiary and a beneficiary premium, which is the responsibility of the PDP member. The Part D beneficiary premium is subsidized by CMS in the case of low-income members. CVS Caremark collects Part D insurance premiums from beneficiaries and CMS then recognizes them ratably as revenue over the period in which members are entitled to receive benefits.

63. In addition to the Part D insurance premiums, CVS Caremark's net revenues

include co-payments, deductibles and co-insurance (collectively, the "Member Co-Payments") related to PDP members' actual prescription claims. CMS subsidizes a portion of these Member Co-Payments by paying CVS Caremark an estimated prospective Member Co-Payment subsidy each month. The prospective Member Co-Payment subsidy amounts received from CMS are also included in CVS Caremark's net revenues, and represented 2.6%, 3.5% and 1.3% of CVS Caremark's consolidated net revenues in 2010, 2009 and 2008, respectively. If the prospective Member Co-Payment subsidies received differ from the amounts based on actual prescription claims, CVS Caremark records the difference as either accounts receivable or accrued expenses.

64. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") created a drug subsidy program available to certain employer, union and other group plans that provide retiree coverage to Medicare Part D eligible individuals that is at least equivalent to Medicare Part D coverage. The Part D retiree drug subsidy is equal to 28% of drug costs, and is currently (until 2013) tax-free. CVS Caremark's net revenues also include these retiree drug subsidies paid by CMS.

C. The "Medical Card System" Entities

1. Medical Card System, Inc.

65. Medical Card System, Inc. (hereafter, "MCS") is a for profit corporation registered in the Commonwealth of Puerto Rico, whose principal place of business is located at 225 Ponsce de Leon Avenue, Hato Rey, Puerto Rico.

66. MCS is the second largest health administration and health insurance company in Puerto Rico with more than 725,000 commercial, Medicare, and Puerto Rico Medicaid ("Reforma") insured lives. MCS provides health plans to more than 1,000 companies and covers over 150,000 employees and family members. MCS has been operating in Puerto Rico for over

26 years and employs more than 500 people.

67. Among other health services, MCS provides medical plans in Puerto Rico, Medicare Part D coverage through both PDPs and Medicare Advantage Part D Plans ("MA-PDs") which are offered through MCS's subsidiary, MCS Life Insurance Company. MCS also provides Part D coverage to employers who offer Part D benefits through employer plans to whom Part D retiree drug subsidies would apply.

68. In addition, MCS, through its affiliate, MCS Advantage, Inc., also provides managed Medicare coverage. MCS Classicare healthcare plans provide MA-PD coverage to beneficiaries receiving Medicare Part C (managed care) coverage through MCS Advantage, Inc.

69. MCS provides pharmacy benefits to dual eligible Medicare Part D and Medicaid beneficiaries, including members impacted by Low Income Subsidy grants available to Medicare Part D beneficiaries living in the United States territories.

2. MCS Life Insurance Company

70. MCS Life Insurance Company (hereafter "MCS Life") is a for profit corporation registered in the Commonwealth of Puerto Rico, whose principal place of business is located at 225 Ponsce de Leon Avenue, Hato Rey, Puerto Rico.

71. MCS Life is a subsidiary of MCS. At all times relevant hereto, MCS Life provided Medicare Part D coverage to plans offered by MCS.

72. In November 2004, CMS approved MCS Life's request to offer managed care coverage to Medicare beneficiaries in the San Juan, Puerto Rico metro area and in 50 other municipalities in Puerto Rico, where approximately 325,000 Medicare beneficiaries lived.

73. Since January 1, 2006, MCS Life has participated with CMS as a Medicare Part D Plan Sponsor, providing Medicare Part D coverage to plans offered by MCS.

74. From January 1, 2006 through at least September 2007, pursuant to the terms of a contract executed between them ("the Part D Contract"), CVS Caremark and SilverScript provided Medicare Part D PBM services to MCS Life for health insurance plans offered by MCS.

75. At the time of the Part D Contract in early 2006, MCS Life offered Part D benefits through a number of PDPs and MA-PDs, including: MCS Classicare Rx (PDP); MCS Classicare Rx2 (PDP); Classicare (MA-PD); Platino MAPD; and Platino SNP.

76. MCS Life developed formularies for the following Part D Plans: MCS Classicare Rx (PDP); MCS Classicare Rx2 (PDP); and MCS Classicare PFFS (Premium MA-PD); MCS Classicare Rx Standard (PDP).

77. At the time of the Part D Contract in early 2006, MCS Life also offered Part D benefits to employer plans providing prescription coverage to their retirees. These retiree Plans include: Ela 9.3 (MA-PD); Ela Rx (PDP), Ela Rx2 (PDP), BPPR (MA-PD), BPPR Premium ((MA-PD), Avon (MA-PD), BASF (MA-PD), Island Finance (MA-PD), Prossam Rx (PDP).

78. In or about February 2007, MCS retained Relator Spay's company, Pharm/DUR, to perform a comprehensive audit of the Medicare Part D PBM services provided for MCS Life by SilverScript.

III. JURISDICTION AND VENUE

79. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S. C. § 1367 and 31 U.S.C. § 3732.

80. This Court has personal jurisdiction and venue over Defendants pursuant to 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States.

Moreover, the Defendants can be found in, and reside and transact business in, this District.

81. Venue is also proper in this District pursuant to 31 U.S.C. § 3731(a) because Defendant CVS Caremark can be found in, and conducts business in this District. At all times relevant to this Complaint, Defendant CVS Caremark regularly conducted substantial business within the Eastern District of Pennsylvania, maintained employees and offices in Pennsylvania, and made significant sales within Pennsylvania, where its facilities include hundreds of retail stores, one specialty pharmacy store, and two specialty mail order facilities.

82. In addition, the statutory violations as alleged herein, occurred within this District.

IV. APPLICABLE LAW

A. The Medicare Part D Program: Prescription Drug Coverage

83. The Medicare Part D Program provides beneficiaries with assistance in paying for out-patient prescription drugs. This massive out-patient prescription drug benefit was added to Medicare by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, ("MMA"), Pub. L. 108-173 (Dec. 8, 2003), 42 U.S.C. § 1395w-101 et seq. (2004 supplement), 42 C.F.R. § 423.506.

84. The MMA provides that Medicare beneficiaries entitled to Medicare benefits under Part A or enrolled in Part B are eligible for Medicare Drug benefits under Part D. Section 1860D-2 of the Social Security Act, 42 U.S.C. 1395w-102, provides for out-patient prescription drugs to be provided to Medicare beneficiaries to be called "Medicare Part D" benefits which began in January 2006.

85. If a drug, as prescribed and dispensed or administered to an individual, is covered for that individual under Medicare Part A or Part B, then the drug is not covered under Part D. 42 U.S.C. § 1396w-102(e)(2)(B), Section 1860D-2(e)(2)(B) of the Social Security Act.

86. The MMA also created a subsidy available to certain employer, union, and other group Plans that provide retiree coverage to Part D eligible individuals that is at least equivalent to Part D coverage (the "retiree drug subsidy"). Section 1860D-22 of the Social Security Act, 42 U.S.C. § 1395w-132. Thus, the Federal government pays a Part D retirement subsidy to employers whose Plans provide prescription drug benefits similar to Part D Plans for their retired employees.

B. Entities Operating in the Medicare Part D System

1. Part D Sponsor

87. Unlike coverage in Medicare Parts A and B, Part D coverage is not provided within the traditional Medicare program. Instead, Medicare beneficiaries must affirmatively enroll in one of many hundreds of Part D Plans offered by private companies such as the Caremark Defendants. See, MMA, Sections 1102, 1860D-1 through 1860D-42, and 1871 of the Social Security Act; 42 U.S.C. §§ 1302, 1395w-101 through 1395w-152, and 1395hh.

88. A Medicare Part D Plan Sponsor ("Part D Sponsor"), whether it be a Part D Plan or PDP, or a Medicare Advantage Prescription Drug Plan or MA-PD, is an entity that is certified as meeting the requirements of Part D and that contracted with CMS to provide Part D benefits. Section 1860D-41, 42 U.S.C. § 1395w-151(a)(13) and (14)(B). The term "Part D Sponsor" also includes employer and union-sponsored plans which offer qualified Part D prescription coverage. 42 C.F.R. § 423.4.

89. Under Part D, the process begins with the health insurance company submitting a certified application to CMS to participate as a Part D Plan Sponsor to provide prescription drug coverage to qualifying Part D Plans. 42 C.F.R. §§ 423.502, 423.265 and 423.272. That application is a prerequisite for contracting with CMS as a Part D Plan Sponsor. 42 C.F.R. §

423.504(b). CMS is authorized to deny an application to qualify as a Part D Sponsor based on the applicant's failure to comply with the terms of a previous year's contract with CMS, even if the applicant is currently meeting all of the requirements for Part D participation. 42 C.F.R. 423.503(b).

90. The Part D Plan Sponsor must also agree to comply with the requirements and standards of Part D and all the terms and conditions of payment. Section 1860D-12, 42 U.S.C. § 1395w-112(b)(1).

91. The contract between the Part D Plan Sponsor and CMS must include the elements listed in 42 C.F.R. § 423.505(b), including compliance with the reporting requirements as set forth in § 423.514 and the requirements set forth in § 423.329(b) for submitting drug claims and related information to CMS for its use in risk adjustment calculations. The Part D Plan Sponsor must also expressly agree to provide CMS with the information CMS determines is necessary to carry out payment provisions. 42 C.F.R. § 423.505(b)(8) and (9).

92. A Part D Plan Sponsor, in contracting with CMS, also expressly "agrees to comply with Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law [and] the False Claims Act (32 U.S.C. §§ 3729 et seq.)." 42 C.F.R. 423.505(h)(1).

93. To qualify for Part D payments from CMS, before each plan year, each approved Part D Plan Sponsor must submit a bid, certified by an actuary, for each Part D Plan it will offer. 42 C.F.R. § 423.265. The bid contains a per member per month ("PMPM") cost estimate to provide Part D benefits to an average Medicare beneficiary in a particular geographic area. CMS considers both the tiered formulary structure and utilization management program components of the Part D Plan Sponsor's bid. 42 C.F.R. § 423.272(a)(2). From those Part D Plan bids, CMS

calculates nationwide and regional benchmarks which represent an average PMPM cost. If the Part D Plan Sponsor's bid exceeds the benchmark, the Plan Member must pay the difference.

94. Once approved, the Part D Plan Sponsor may market its Plans to eligible Medicare Part D beneficiaries, but CMS sets restrictions on marketing and enrollment. 42 C.F.R. § 423.50.

95. During each benefit year, CMS pays the Part D Plan Sponsors estimated payments on a monthly basis. In turn, Part D Plan Sponsors provide CMS with documentation of their actual costs. One required method for Part D Plan Sponsors to provide actual cost information to CMS is by submitting a Prescription Drug Event ("PDE") record for every prescription that is filled for a Plan Member.

96. Once enrolled, each Part D Plan participant pays a monthly premium to the Part D Plan, as determined under the Part D Regulations. 42 C.F.R. §§ 423.153 and 423.293.

97. In the year following each benefit year, CMS reconciles a PDP Sponsor's actual prescription drug costs as derived from its PDE records against the Sponsor's bid. If a PDP sponsor's actual costs exceed the estimated costs, the Sponsor may be able to recoup some of its losses through a risk-sharing arrangement with CMS. Conversely, if a Part D Plan Sponsor's estimated costs exceed its actual costs, the Sponsor may have to pay back some of its estimated payments to CMS.

98. Thus, CMS pays the Part D Sponsor under Medicare Part D. The Part D Sponsor then pays the Part D Plan pharmacies for prescriptions, less the Medicare beneficiary's co-pay.

99. The Part D Sponsor is required to make several significant and material express certifications to CMS regarding its submission of Part D data used for payment:

1. Certification of Data that Determines Payment: "As a condition for receiving a monthly payment ... the Part D Plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies." 42 C.F.R. § 423.505(k)(1).

2. Certification of Enrollment and Payment Information: "The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(2).

3. Part D Sponsor Certification of Claims Data: "The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under §

423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

4. Certification of Bid Submission Information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265." See, 42 C.F.R. § 423.505(k)(4).

100. The Part D Sponsor is required to expressly certify to the accuracy and completeness of allowable costs for risk corridor and reinsurance information and of data for price comparison that it submits to CMS. 42 C.F.R. § 423.505(k)(5) and (6).

101. Particularly relevant here, the entity submitting the Part D payment data, the Part D Sponsor or PBM, must also make express certifications to CMS regarding Part D data used for payment. The Federal regulations provide that the entity submitting Part D claims data, the Part D Sponsor or the PBM, must execute the following certification:

> **"If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement."**

42 C.F.R. § 423.505(k)(3), (emphasis added).

2. First Tier, Downstream, and Related Entities

102. The regulations governing Part D benefits define major entities with which a Part D Sponsor may contract. 42 C.F.R. § 423.505(i). See also CMS Prescription Drug Manual Chapter 9 - Part D Program to Control Fraud, Waste and Abuse, 40 – Part D Sponsor Accountability and oversight, p. 12. CMS has described these entities as "pharmacies or other providers, related entities, contractors, subcontractors, first tier and downstream entities."

103. A "First Tier Entity" is a party with whom the Part D Sponsor has a written contract "acceptable to CMS with a Sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D." 42 C.F.R. § 423.501.

104. In most cases, the "First Tier Entity" will be a pharmacy benefits manager, PBM. CMS Prescription Drug Manual Chapter 9 - Part D Program to Control Fraud, Waste and Abuse, 40 – Part D Sponsor Accountability and oversight, p. 12.

105. A "Downstream Entity" is any entity with a written contract with the Part D Sponsor "below the level of the arrangement between a Sponsor and a first-tier entity." 423.501. Downstream entities include the ultimate service providers of health and administrative services, i.e., pharmacies and further downstream below the pharmacy, the pharmacist. CMS Prescription Drug Manual Chapter 9 - Part D Program to Control Fraud, Waste and Abuse, 40 – Part D Sponsor Accountability and oversight, p. 12.

106. By way of simple illustration, the Part D Sponsor (here, Defendant MCS Life) enters into a contract with PBM (here, the CVS Caremark Defendants). The PBM is the First Tier Entity. The PBM then contracts with participating pharmacies to provide the dispensing services. The pharmacies are Downstream Entities. If the pharmacies then contract with

pharmacists, the pharmacists would also be Downstream Entities. CMS Prescription Drug Manual Chapter 9 - Part D Program to Control Fraud, Waste and Abuse, 40 – Part D Sponsor Accountability and oversight, p. 12.

107. A Related Part D entity is "an entity that is related to the Part D Sponsor by common ownership or control and either performs some of the Sponsor's management functions under contract or delegation, furnishes services to Medicare enrollees under oral or written agreements, or certain lease arrangements with the Sponsor. This includes, for example, where a Sponsor is the parent company of its own in-house PBM." 42 C.F.R. § 423.501; CMS Prescription Drug Manual Chapter 9- Part D Program to Control Fraud, Waste and Abuse, 40 – Part D Sponsor Accountability and oversight, p. 13.

C. Summary of the Part D Process - Adjudicating Prescriptions

108. Most Medicare beneficiaries who elect Part D coverage are responsible for certain costs, which may include a monthly premium, an annual deductible, and/or co-pays.

109. After receiving a prescription from his or her doctor, the Part D Plan beneficiary goes to a retail pharmacy and presents the prescription to the pharmacist (or submits a prescription to a mail order pharmacy).

110. The pharmacy receives the prescription and participant's information, and then submits required data elements to the Plan or its PBM to confirm Medicare Part D enrollment and identify co-pays. This typically takes place via real-time data transmissions between the pharmacy and the PBM.

111. The pharmacy must also perform pharmacy services, as required by state law. For example, in Pennsylvania, pharmacy services include verifying the prescription being prepared, performing checks for allergic reactions and drug interactions, and retaining the

prescription on file which identifies the prescriber.

112. Where the Part D Plan Sponsor uses a PBM, the PBM reviews the pharmacy's initial data submission to conduct pre-dispensing/point-of-sale reviews of the Part D claim as required by Federal law and regulations and pursuant to the contract between the Plan Sponsor and the PBM.

113. If the claim for the prescription is not rejected by the Sponsor or PBM, the pharmacy receives payment authorization and co-pay information and dispenses the prescription to the Part D beneficiary. The beneficiary pays the co-pay to the pharmacy and receives the prescription. At the time of the initial data submission, the pharmacy transmits to the Plan Sponsor or PBM certain data elements specified by contract between the pharmacy and the Plan Sponsor or PBM. These data elements would include, among other things, the beneficiary information, prescriber information, and drug information.

114. Once the PBM or Plan receives that data from the pharmacy, the PBM or Plan Sponsor submits the claim data to CMS via a Prescription Drug Event ("PDE") record.

115. The Part D Plan or its PBM is required to also submit other data to CMS, i.e., enrollment information, bid submission data, costs for risk corridor and reinsurance information, and data for price comparison. 42 C.F.R. 423.505 (k).

116. Part D Sponsors are also required to submit other information to CMS regarding costs of providing Part D coverage, i.e., administrative costs, rebates, and other information.

117. Sections 1860D-15(c) (1)(C) and (d)(2) of the MMA require Sponsors to submit data and information necessary for CMS to carry out payment provisions. For every prescription filled, the Part D Sponsor or its PBM prepares and submits a PDE record to CMS.

118. The PDE record contains prescription drug cost and payment data that enables

CMS to make payments to Plans and otherwise administer the Part D benefit.

D. CMS Part D Payments Based on PDE Claims Data Submitted to CMS

119. Sections 1860D-14 and 15 of the MMA provide that CMS pay Plans for Part D benefits through subsidies and risk sharing.

120. CMS pays a direct subsidy (a capitated payment) to the Part D Plan (PDP) in the form of advance monthly payments equal to the Part D Plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus a monthly beneficiary premium as determined in § 423.286. 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D Plan Sponsor for each Part D beneficiary enrolled in the Plan.

121. In addition to the direct subsidy, through low-income subsidies, CMS makes payments to the Part D Plan for premium and cost sharing subsidies on behalf of certain subsidy-eligible individuals as provided in § 423.780 and § 423.782. These types of premium and cost-sharing subsidies for qualifying low-income individuals are called "Low-Income Cost Sharing Subsidies" (LICS), and are documented and reconciled using PDE data submitted to CMS. CMS "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, page 41, Section 10.1. In the United States Territories, CMS issues grants in lieu of LICS.

122. Through retroactive adjustments and reconciliations, CMS also reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343. See 42 C.F.R. § 423.315(f). In other words, CMS reconciles payments received by Part D Plans at the end of the year to determine whether additional funds are due to or from the Part D Plan Sponsor.

123. For private fee-for-service plans (as defined by § 422.4(a)(3)) that offer qualified prescription drug coverage, CMS determines the amount of reinsurance payments to be made to them as provided under § 423.329(c)(3). See 42 C.F.R. § 423.315(g).

124. Thus, throughout the year, CMS makes prospective payments to Part D Sponsors for three subsidies based on the Sponsors' approved bids: (1) the direct subsidy (a monthly capitated payment) designed to cover the Sponsor's cost of providing the benefits; (2) the low-income cost-sharing subsidy (the Federal government's portion of cost-sharing payment for certain low-income beneficiaries); and (3) the reinsurance subsidy (the Federal government's share of drug costs for beneficiaries who have reached catastrophic coverage).

125. A Part D Sponsor may also receive other payments from CMS resulting from year-end reconciliations and adjustments.

126. Pursuant to 42 C.F.R. § 423.343, after the close of the plan year, CMS is responsible for reconciling the prospective payments to the Part D Sponsor's actual allowable costs to calculate final payments and risk sharing amounts. CMS determines the Plan's actual allowable costs by relying upon certain data elements submitted by Sponsors in their PDE records.

127. CMS specifically relies upon and uses the following PDE cost and payment fields in its year end reconciliation: gross drug cost above out-of-pocket threshold, gross drug cost below out-of-pocket threshold, low-income cost-sharing subsidy, and covered D Plan paid amount (the four PDE data elements). The Sponsor, or its PBM, calculates the four data elements from the point-of-sale claims data submitted by the pharmacy using instructions provided by CMS.

128. In order to receive Part D funds from CMS, Part D Sponsors, their authorized

agents, employees, and contractors (including pharmacies) are required to comply with all applicable Federal laws, regulations, as well as CMS instructions. 42 U.S.C. § 1860D-12(b)(1); 42 C.F.R. § 505(i)(4)(iv).

E. Medicare Part D Payments to Part D Sponsors Are Expressly Conditioned Upon Submission of Accurate, Complete and True PDE Data

129. As an express condition of payment by CMS, all Part D Sponsors must submit data and information necessary for CMS to carry out the payment provisions found in § 1860D-15(c)(1)(C) and (d)(2) of the Social Security Act. Thus, CMS payments to a Part D Sponsor are expressly conditioned upon the Sponsor providing "information to CMS that is necessary to carry out this subpart, or as required by law." 42 C.F.R. § 423.322 (a).

130. Accordingly, all contracts between Part D Sponsors and CMS must contain the following term: the Part D Sponsor must agree to: "provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this Part (or for fallback entities, the information necessary to carry out the payment provisions in subpart Q of this Part)." 42 C.F.R. § 423.505(b)(9).

131. In order to carry out these payment provisions, (42 C.F.R. § 423.329 determination of payments"), CMS mandatorily requires Part D Sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B and other information as CMS determines necessary. 42 C.F.R. § 423.329(b)(3)(i) (data collection).

1. Required Data Elements for PDE Records

132. On April 27, 2006, CMS issued "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)", in which CMS identified a set of data elements, Prescription Drug Event ("PDE") data, which are necessary to determine payments to Medicare Part D PDP Sponsors. The Part D Plan must submit a PDE record for each and every

dispensing event. "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, page 9.

133. The PDE record is a summary record that documents the final adjudication of a dispensing event by a PBM based upon claims received from pharmacies. "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, page 9.

134. There are 37 set data elements in the required data set for all PDE records: 15 elements for the National Council for Prescription Drug Program ("NCPDP") billing transaction, 5 data elements for the NCPDP billing response transaction, and 17 data elements identified by CMS for purposes of administering Part D. "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, page 9.

135. Most of the Medicare Part D PDE data elements are the same elements developed by the NCPDP, which have been used for decades by PBMs, pharmacies, and other providers when submitting Medicare and Medicaid claims for prescription drugs to CMS for payment. In its "Instructions for Submitting Prescription Drug Event Data," dated 4/27/2006, at page 11, CMS stated: "Most data elements represent existing NCPDP fields where we employ the same definition and field values that are currently in use per the NCPDP version 5.1 drug claim standard." NCPDP version 5.1 was approved in September of 1999.

136. When CMS identified "Data Elements for PDE Records," it clearly stated, and all parties were on notice, that submission of PDE data is an express condition of payment: "In this section, we list the required data elements that must be submitted on PDE records for payment ... This Section defines each data element and its specific potential use for CMS's payment process." CMS "Updated Instructions: Requirements for Submitting Prescription Drug Event

Data (PDE)," 4.27.2006, page 11, Sec. 2.

137. CMS further described the purpose of the various PDE data elements as follows: "Much of the data, especially dollar fields, will be used primarily for payment. However, some of the other data elements such as pharmacy and prescriber identifiers will be used for validation of the claims as well as for other legislated functions such as quality monitoring, program integrity, and oversight." CMS "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, pages 5-6, Section 1.4.

138. CMS provided that the reporting "requirements apply to all Part D Plans." "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, page 5. Thus, CMS data reporting requirements and instructions apply to all Part D Plans (PDPs), Medicare Advantage Part Plans (MA-PDs), and any other entity providing Part D benefits.

2. Part D Claims – Certification of Truth and Accuracy

139. Sponsors and their subcontractors, i.e., PBMs, when submitting Part D PDE data to CMS, must certify that all claims are true and accurate. CMS Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste, and Abuse, Section 80.1, p.67, citing 42 C.F.R. § 423.505(k)(3).

140. Thus, CMS's Regulations for the submission of Part D PDE data place the legal risk of submitting invalid Part D claims data squarely with the submitting or generating entity: "CMS requires that **any entity that generates [Part D] claims data** on behalf of a Sponsor" must both: **"certify to CMS the accuracy, completeness, and truthfulness of that data;" and "acknowledge that the data will be used for purposes of obtaining Federal reimbursement."** See "Prescription Drug Benefit Manual, Chapter 9 – Part D Program to

Control Fraud, Waste, and Abuse," page 16, Section 40-2; citing 42 C.F.R. § 423.505(k)(3)) (emphasis added).

141. In keeping with the requirements of 42 C.F.R. § 423.505(k)(3) and CMS Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste, and Abuse, Section 80.1, p.67, Sponsors and their subcontractors who submit Part D PDE data to CMS must certify that it is true and accurate.

142. Since January 2006, this express certification of Part D PDE data has been included in CMS's Electronic Data Interchange (EDI) Agreement (or a similar document). The EDI Agreement must be executed in order for an eligible organization to submit PDE data electronically to CMS. The EDI is executed by Medicare Plans offering Part D prescription drug benefit and/or the Part D PMBs who submit PDE data on behalf of Part D Sponsors. The certification on the Part D EDI Agreement contains the following (or similar) language:

> **"By signing below, the eligible organization certifies that each submission of PDE data pursuant to this Agreement will be accurate and complete to the eligible organization's best knowledge, information and belief."**

143. Defendants, through subsidiary Part D sponsors and/or PBMs, have made such explicit certifications of PDE data from 2006 to the present. They continue to make these certifications on an ongoing basis to the Government.

144. CMS also requires, through the EDI Agreement, that the Part D Sponsor both: "ensure that every electronic entry can be readily associated and identified with an original source document (e.g., an original drug claim) …," and "retain all original source documentation pertaining to any such particular Medicare prescription drug event for a period of at least 10 years after the prescription drug event is received and processed."

145. CMS recognizes that the submission of "inaccurate or incomplete prescription